

ORIGINAL

Before the
FEDERAL COMMUNICATIONS COMMISSION
 Washington, DC 20554

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MAR 27 2003

Federal Communications Commission
 Office of secretary

In the Matter of)

Biotronik, Inc.)

Request for Waiver of the Frequency
 Monitoring Requirements of the
 Medical Implant Communications
 Service Rules)

ET 03-92

REQUEST FOR WAIVER

Biotronik, Inc., ("Biotronik"), by its attorneys and pursuant to Section 1.3 of the Commission's rules,¹ hereby requests a permanent waiver of the frequency monitoring requirements of the Medical Implant Communications Service ("MICS") rules in order to allow its cardiac implant devices to emit periodic scheduled transmissions.² This request for permanent waiver applies to Biotronik's current line of cardiac implant devices³ and also is intended to cover like devices in the future, which have the periodic scheduled transmission feature.

Biotronik requests that this waiver request be expedited or, if that is not possible, Biotronik requests an interim waiver of the frequency monitoring requirements for the periodic transmissions with immediate effect. The Commission should expedite consideration of this waiver request so that cardiac implant patients

¹ See 47 C.F.R. § 1.3.

² See 47 C.F.R. § 95.628(a).

³ Biotronik's current line of cardiac implant devices that offer the periodic scheduled transmission feature consists of the Philos DR-T pacemaker, and the Belos VR-T and Belos DR-T implantable cardioverter defibrillators.

may continue to receive the medical benefits of the periodic transmission mode, which is an essential element of Biotronik's remote monitoring technology. Expedition of this request or an interim waiver is necessary because Biotronik products without the periodic messaging capability are not immediately available.⁴ While the instant waiver request remains pending, there are hundreds of patients unable to benefit from the clinical advantages provided by Biotronik's Home Monitoring technology.

I. BACKGROUND

As the Commission is aware, Biotronik manufactures cardiac implant devices that have the capability of transmitting operational, diagnostic, and therapeutic information associated with the use of the devices by patients to healthcare professionals via the cellular telephone network. Previously, this type of data could be collected only through regular office visits by the implant patient to his or her physician once every six months or annually. In contrast, the remote monitoring technology offered by Biotronik's implants allow patient diagnostic and trend data, and other medically valuable information, to be transmitted instantaneously from the implant at any time from almost anywhere in the United States.

⁴ The Commission's decision on the periodic transmissions used by the Philos DR-T device requires that the device's periodic transmissions be "turned off" while event and patient-initiated transmissions may continue to function. See *In re Biotronik, Inc., Equipment Authorization for the Medical Implant Communications Service, Memorandum Opinion and Order*, FCC Identifier No. PG6BA01, FCC 03-32, ¶¶ 11 and 15 (rel. Feb. 25, 2003) ("Philos MO&O"). In order to comply with that decision, Biotronik has to rewrite the implant device's firmware so as to disable the periodic transmission mode, while preserving the other two transmission modes. Such a rewrite of system firmware is a complicated and time-consuming process alone, but there also are two additional processes required after the firmware is rewritten. First, Biotronik has to validate all of the software used in the device. Such validation encompasses not only the changes made to the firmware, but also all existing device features and functions, in order to ensure that the changes does not have an unanticipated adverse impact on the existing firmware. Secondly, the FDA has to approve the new software change as a "PMA supplement." Upon a showing of extraordinary urgency, this process could be completed in two months, but approval usually takes six months. Thus, at best, it is not possible for Biotronik to use its cardiac implant devices in the manner contemplated by the Commission for 8 to 12 months.

Signals transmitted by the implanted device are received by a special-purpose "cellphone" that the patient must keep within approximately 2 meters of the implanted device. Once received, the external device transmits the information via cellular telephone frequencies to Biotronik's service center, where it is then forwarded to the patient's physician

To be clear, given the system configuration described above, the transmissions from Biotronik's implants cannot be used for purposes of immediate response to life-threatening situations. Nonetheless, the data collected has proven to be extremely useful in allowing physicians to monitor the implant patient's changing cardiac condition over time and to intervene in the patient's treatment if needed. Thus, Biotronik's devices represent a medically-valuable, cost-effective, and efficient alternative to traditional medical implant devices that do not offer remote monitoring capabilities.

In general, Biotronik's devices offer three modes of transmission. First, a transmission occurs when certain cardiac events or changes in device status are detected by the implant device itself (known as "event messaging"). Second, a transmission can be activated manually when the implant patient has discomfort or concern. The Commission has determined that both of these modes of transmission comply with the medical implant event requirements contained in Section 95.628(b) of the MICS rules.⁵

Biotronik's medical implant devices also have the capability of offering regularly scheduled, periodic transmissions, which are preprogrammed by the implant patient's physician and occur at regular intervals. Such periodic transmissions are

⁵ See Letter Order from Mr. Bruce A. Franca, Deputy Chief, Office of Engineering and Technology, FCC ID. No. PG6BA0T (Mar. 8, 2002) at 2 ("OET Letter Order"), *aff'd*, In *re* Biotronik, Inc., Equipment Authorization for the Medical Implant Communications Service, Memorandum Opinion and Order, FCC Identifier No. PG6BA0T, FCC 03-32, ¶ 11 (rel. Feb. 25, 2003).

viewed as highly efficacious by the medical community.⁶ Nevertheless, on February 25, 2003, the Commission found that such “preprogrammed, regularly scheduled transmissions on a single channel without prior frequency monitoring do not comport with the rules established for MICS.”⁷ As a result, to use this feature, Biotronik would, absent a waiver, have to re-engineer and redesign all of its implant devices to incorporate bidirectional technology simply to provide the periodic mode of transmissions.

In addition, the Commission found that there might be a potential for interference to the periodic transmissions emitted by Biotronik’s devices, which could unreasonably impact other users of the 402-405 MHz band, which was of particular concern to NTIA with respect to the federal users who have primary status in the MICS frequency band.⁸

Finally, the Commission denied Biotronik’s request for waiver of the MICS rules to allow such transmissions because Biotronik did not “demonstrate that there is a hardship or burden in complying with [the MICS rules], or that a compliant device could not just as effectively serve patients needs.” NTIA expressed a similar concern¹⁰

⁶ See Letters to Mr. Edmond Thomas, Chief, Office of Engineering Technology from Yakima Heart Center (Apr. 11, 2002); New Jersey Pacemaker and Defibrillator Evaluation Center, Inc. (Apr. 11, 2002); Stanford University Medical Center (Apr. 15, 2002); Covenant Health System (Apr. 15, 2002); Legacy Heart Institute (Apr. 17, 2002); University Hospital of Cleveland (Apr. 17, 2002); Providence Everett Medical Center (Apr. 19, 2002); and Cardiology of Georgia, P.C. (Apr. 25, 2002), FCC Identifier No. PG6BA0T, all filed in support of Biotronik’s remote monitoring technology.

⁷ *Philos MO&O* at 7/15

⁸ The 402-405 MHz band is primarily allocated for federal use of the Metajids service. See *id.* at ¶18; see also Letter to Mr. Edmond J. Thomas, Chief, Office of Engineering and Technology, from Mr. Frederick R. Wentland, Acting Associate Administrator, NTIA (Nov. 5, 2002) (“NTIA Letter”)

⁹ *Philos MO&O* at ¶18.

¹⁰ See NTIA Letter.

The instant request for waiver responds to the concerns expressed both by the Commission and NTIA.

II. GOOD CAUSE EXISTS FOR, AND THE PUBLIC INTEREST WOULD BE SERVED BY, WAIVER OF THE FREQUENCY MONITORING REQUIREMENTS OF THE MICS RULES.

The Commission has authority to waive its rules if there is "good cause" to do so.¹¹ The Commission may exercise its discretion to waive a rule "where particular facts would make strict compliance with the rule inconsistent with the public interest."¹² However, a waiver is appropriate "only if special circumstances warrant a deviation from the general rule," and the waiver "must be founded on an appropriate general standard."¹³ In deriving that standard, the Commission should "in some way take into account considerations of hardship, equity, or more effective implementation of overall policy."¹⁴ As demonstrated below, good cause exists for, and the public interest would be served by, granting the instant waiver request.

A. THERE IS NO REALISTIC RISK OF INTERFERENCE CAUSED BY OR TO BIOTRONIK'S DEVICES.

Biotronik's cardiac medical implant devices represent no risk of interference to other MICS users or to primary users of the 402-405 MHz band. Likewise, Biotronik's devices are not susceptible to interference that may be caused by such users.

1. Biotronik's Devices Will Not Interfere With Other MICS Users Or With Primary Users Of The 402-405 MHz Band.

The scheduled periodic transmissions emitted by Biotronik's medical implant devices will not cause harmful interference to other MICS users or to primary federal users of the 402-405 MHz band. Transmissions from Biotronik's devices last less than

¹¹ 47 C.F.R. § 1.3.

¹² *Northeast Cellular Telephone Co. v. FCC*, 897 F.2d 1164, 1166 (D.C. Cir. 1969), citing *WAIT Radio v. FCC*, 418 F.2d 1153, 1159 (D.C. Cir. 1969).

¹³ *Id.* (internal quotations omitted).

¹⁴ *WAIT Radio v. FCC*, 418 F.2d 1153, 1159 (D.C. Cir. 1969).

one second (80msec for Philos DR-T and 270msec for Belos VR-T and DR-T).

Moreover, the devices have a range of approximately two meters and operate at ultra-low power levels, peaking at approximately 6.27 nanowatts, which is much less than the maximum EIRP of 25 microwatts ordinarily authorized for MICS transmitters.¹⁵

Neither the Commission nor NTIA has expressed concern that the operation of the Biotronik's devices in the manner described above presents any realistic potential for interference to MICS users or to the primary federal users of the 402-405 MHz band.¹⁶ To the contrary, NTIA's principal concern, and perhaps the Commission's principal concern, seems to be that Metaids transmitters will interfere with Biotroniks devices.¹⁷ As shown below, there is no realistic risk of such interference.

2. Other MICS Users And Federal Users Of The 402-405 MHz Band Will Not Interfere With Biotronik's Devices.

There is no realistic risk of interference caused to Biotroniks devices from other MICS users or from primary users of the 402-405 MHz band, including users of Metaids. In developing its remote monitoring technology, Biotronik took into consideration and accounted for the potential for interference from Metaids and other sources of noise in the 402-405 MHz band, in part because the Food and Drug Administration ("FDA") requires that MICS implants be designed to ensure that interference from impulse, narrowband, and broadband systems in the 402-405 MHz band do not affect the ordinary function of the devices or their transmissions. All of Biotronik's cardiac implant devices have gone through rigorous, FDA-approved testing and have been certified by the FDA. Accordingly, there is no risk that

¹⁵ See *id.*; see also 47 C.F.R. § 95.639(f)(1).

¹⁶ See Philos MO&O at ¶18 ("the interference potential from the Philos DR-t appears to be *de minimis*"); see also OET Letter Order at 3 ("the potential for interference is *de minimis* (about one half second per day total with typical transmissions sent in the early hours of the morning)").

¹⁷ It should be noted that, to the extent this is NTIA's concern, it is a concern that applies equally to all the transmissions from Biotronik's devices, not just the periodic transmissions that were the subject of Biotronik's initial waiver request for the Philos DR-T. In fact, as discussed above, interference need not be a concern with respect to any transmission from Biotronik's devices.

Interference from other users of the 402-405 MHz band will cause Biotronik's devices to malfunction in a manner that would threaten the health and safety of the implant patient.¹⁸

In addition, Biotronik has incorporated several protections into its devices to ensure the integrity of transmissions. Each transmission from a Biotronik device includes the unique serial number of the implant device itself, which corresponds to the serial number of the external receiver also supplied to the patient. Only data that correctly matches the serial number of both the implant and the receiver are forwarded to the responsible physician. Biphase encoding also is used with each digital transmission string to ensure that DC signals will not be misinterpreted as messages from the implant device.

Furthermore, a 16-bit cyclical redundancy check is performed with each transmission string, resulting in a maximum error rate of 0.0015 percent for each transmission. Finally, in order to ensure receipt of the cardiac data transmitted, each device employs a redundant messaging protocol. The primary message is transmitted at the time scheduled by the monitoring physician. Thereafter, six identical messages are transmitted over the course of an hour in eight to ten minute intervals. This redundant messaging produces a 99.999 percent chance of transmission success.

Finally, even in the unlikely event that a transmission from one of Biotronik's devices is unsuccessful due to interference from other users of the 402-405 MHz band, such failure will not affect the health or safety of the implant patient. As explained above, Biotronik's remote messaging technology provides no direct therapy, but is only diagnostic in nature. In addition, remote messaging is not intended to take the

¹⁸ All of Biotronik's implantable products are verified to be immune to all sources of electronic noise through exhaustive testing to regulatory standards. These include IEC 60601-1-2 International standard for electromagnetic compatibility for medical electronic equipment, CENELEC standards EN 45502-2-1 for electromagnetic susceptibility, AAMI standard PC69 EMC test protocol for Active implantable medical devices, as well as electronic article surveillance (EAS) systems testing.

place of traditional emergency health intervention services, such as 9-1-1, but rather is intended to facilitate early intervention in patient treatment. The primary purpose of scheduled periodic messaging is to collect trend data on the patient's cardiac condition over time.

While the transmitted data from Biotroniks implants has medical value and allows the monitoring physician to detect the development of a potentially life-threatening condition early, the loss of one or several transmissions, improbable as that may be, will not have a significant impact on the health or safety of the patient.

B. REQUIRING COMPLIANCE WITH THE FREQUENCY MONITORING REQUIREMENTS OF THE MICS RULES WOULD IMPOSE AN UNDUE HARDSHIP ON BIOTRONIK AND WOULD NOT SERVE THE NEEDS OF PATIENTS.

Now that the Commission has found that Biotronik's periodic transmission feature is not associated with a "medical implant event,"¹⁹ Biotronik would, absent a waiver, have to re-engineer and redesign all of its implant devices to incorporate bi-directional technology simply to provide periodic transmissions in order to comply with the frequency monitoring requirements of Section 95.628(a) of the MICS rules.

When weighed against the negligible risk of interference from or to the periodic transmissions resulting from a grant of this waiver request, such a modification to add bi-directionality would be an unnecessary and costly imposition upon the healthcare community and cardiac patients.²⁰ Moreover, it is doubtful that such a modification is

¹⁹ See *Philos MO&O* at ¶ 15.

²⁰ Given the purpose and nature of periodic transmissions, it would seem that the Commission and NTA should be less concerned with interference to and from periodic transmissions than with interference to and from event and patient-initiated transmissions. As to interference from periodic transmissions, they usually occur during patient sleeping hours, when it is unlikely that other MICS devices will be in two-meter proximity to the patient. As to interference to periodic transmissions, they are repeated a number of times and, even if interfered with, are less time-critical than the other *two* transmission types.

even possible in the current state of the art, which heretofore has prevented Biotronik from implementing this type of bi-directional configuration in its devices.

Presently, Biotronik's devices contain a unidirectional transmitter circuit which provides the wireless link from the implant to the patient's physician. The engineering and design of this unidirectional circuitry and accompanying external transceiver took over five years to develop before the devices reached the market. During that same period, Biotronik attempted to design a bi-directional technology as well, but has been thwarted by the size and battery-life limitations on cardiac implant technology. The same technological challenges hold true for other implantable device manufacturers apparently, as evidenced by the lack of MICS applications for bi-directional equipment authorization since the MICS rules were adopted more than three years ago.

The unidirectional circuitry contained in Biotronik's devices occupies approximately 25 percent of each implant's circuit board, allowing for a compact implant design that offers the value-added feature of remote monitoring. Under normal operating conditions, the unidirectional transmitter in a Biotronik device consumes less than one percent of the implant's battery reserve over the life of the implant. The addition of a bi-directional circuit using present-day technology would upset both of these efficiencies and render Biotronik's devices unusable.

In order to accommodate the extra circuitry necessary to achieve bi-directional capabilities in its devices, Biotronik would have to increase substantially the size of the circuit board in each implant. **As** a result, the overall dimensions of the implants themselves would have to be significantly increased, whereas implant patients and physicians invariably prefer smaller, lightweight devices.

Moreover, a bi-directional circuit would impose additional power demands on the implant's battery reserve, thereby affecting the operating life of the implant itself. If a periodic message cannot be initiated by the implant, then it must await a

transmission from the external transmitter to prompt for such data. In order for a device implanted in a patient's body to detect such a signal it would be required to monitor the 402–405 MHz band on some periodic basis.

Continuous monitoring of the band would deplete the implant's battery in a matter of weeks, rendering the implant device useless. Even if the implant were to monitor the band for only one second every two hours (0.014% duty cycle), such monitoring alone would consume three months of battery reserve over the life of the implant.²¹ Monitoring once every two hours also would significantly delay the transmission of data and cause the external transmitter to propagate a large number of transmissions in its attempt to reach the implantable device, which would greatly increase the number of transmissions in the 402– 405 MHz band.

While Biotronik continues to develop a viable bi-directional device, it will not be able to change the present design of devices for which it seeks this waiver. Such an effort requires a complete redesign of the implants' RF circuitry and involves several additional years of engineering design, development, validation, testing, and regulatory approvals from both the FDA and the FCC before a bi-directional cardiac implant could reach the market. In the interim, patients would be deprived of the proven clinical benefits of the one-way remote monitoring technology for periodic transmissions that is available today with Biotronik's unidirectional devices.

For these reasons, the use of a bi-directional circuit in Biotronik's cardiac implant devices is not feasible at this time. Thus, for the foreseeable future, the only way that cardiac patients will receive the considerable therapeutic benefits associated with periodic transmissions is if the Commission grants the instant request for waiver.

²¹ Calculations based on Biotronik's Philos DR-T pacemaker, which operates with a 1.3Ahr capacity battery producing 2.5 Volt amplitudes, with a quiescent current in the range of 10 microamps to 50 microamps. Supporting an RF circuit with a current draw of 10 milliamps and a duty cycle of 0.014% will consume 3 months of battery capacity.

C. WAIVER IS CONSISTENT WITH THE OBJECTIVES OF THE MICS RULES AND WITH THE PUBLIC INTEREST.

The purpose of the medical implant rules is to make the diagnostic and therapeutic benefits of medical implant devices available to the public while avoiding harmful interference.²² Biotronik's devices, and the scheduled periodic transmissions they offer, unquestionably further these purposes.

As discussed above, scheduled periodic transmissions provide medically valuable trending data and other information that enables physicians to care for their patients more efficiently and effectively. Strict application of the frequency monitoring requirements of the MICS rules to Biotronik's devices would deprive cardiac patients this potentially life-saving technology.

Moreover, as also demonstrated above, there is no realistic risk of interference to or from Biotronik's devices. Thus, Biotronik's devices already serve both primary goals of the MICS rules without frequency monitoring capabilities.


²² See generally *In the Matter of Amendment of Parts 2 and 95 of the Commission's Rules to Establish a Medical Implant Communications Service in the 402-405 MHz Band*, Report and Order, 14 FCC Rld 21040 (1YYY).

III. CONCLUSION

For the foregoing reasons, Biotronik respectfully requests a permanent waiver of the frequency monitoring requirements of the MICS rules to allow its current line of cardiac implant devices, and any like future implant devices, to emit periodic scheduled transmissions. Biotronik further requests an interim waiver with immediate effect of the same rule requirements so that cardiac implant patients may continue receiving the medical benefits of the periodic scheduled transmissions.

Respectfully submitted,

BIOTRONIK, INC.

By: 
Henry Goldberg
Joseph A. Godles

Goldberg, Godles, Wiener & Wright
1229 Nineteenth Street, N.W.
Washington, DC 20036
(202) 429-1900

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DECLARATION OF MARK JOHNSON

I, Mark Johnson, do hereby state under the penalty of perjury of the laws of the United States as follows:

1. I am the Director of U.S. Marketing for Biotronik, Inc. ("Biotronik")
2. I have read the Request for Waiver of Biotronik, and the facts set forth therein are true and correct to the best of my knowledge.



Mark Johnson

March 27, 2003